

| | | |
|---------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Document ID: ROPP-0061 | Title: Guidelines for Dispensing Controlled Substances | |
| Parent Documents: N/A | | |
| Effective Date: See Document Information Page | Last Review Date: See Review and Revision History Section | Business Process Owner (BPO): Sr Director, Prof Svcs, Patient Care Programs |
| Exhibit(s): N/A | | |
| Document Type: Policy and Procedure | | |

PURPOSE

Pharmacists must exercise their professional judgment to meet potentially conflicting challenges posed by the therapeutic imperative to optimize outcomes and the regulatory imperative to prevent drug diversion. State and federal laws and regulations impose a corresponding responsibility on Pharmacists to dispense medicine only for legitimate medical purposes and CVS Health® seeks to ensure that its Pharmacists are fulfilling that corresponding duty at all times.

CVS Health expects and supports decisions by its Pharmacists to *not* fill prescriptions if, in the sound exercise of their professional and clinical judgment they believe or suspect that the prescription was not issued for a legitimate medical purpose by a Practitioner acting in the usual course of professional practice.

SCOPE

This policy and procedure applies to all CVS Pharmacy® Retail stores.

POLICY

Below are some important guidelines for Pharmacists:

1. You should suspend filling ***all controlled substance prescriptions*** from Practitioners you believe or have reason to suspect are not issuing prescriptions for legitimate medical purposes in the course of a valid doctor/patient relationship. Notify your Field (District Leader or Pharmacy Supervisor) and Divisional Professional Practice Leader of such action.
2. You should exercise particular caution before filling a prescription:
 - a. If you believe or have reason to suspect that the Practitioner has not issued the prescription for a legitimate medical purpose in the course of a legitimate doctor/patient relationship, regardless of whether the prescription is otherwise “valid” on its face;
 - b. From Practitioners who prescribe the same medication in the same dosage amounts to ***most or all*** of their patients (e.g., oxycodone 30mg, 180 dosage units) - the use of prescriptions that are preprinted or stamped with the drug type and amount should be cause for concern;
 - c. From Practitioners who ***routinely*** prescribe the same combination of drugs for pain treatment for most ***or all of their patient, particularly where DEA has identified that combination as potentially abused*** (e.g., oxycodone, alprazolam and Soma);

| | |
|---------------------------|-----------------------------------------------------------|
| Document ID: ROPP-0061 | Title: Guidelines for Dispensing Controlled Substances |
|---------------------------|-----------------------------------------------------------|

- d. From Practitioners who you are aware do not take insurance or whose patients have insurance but always insist on paying cash for their prescriptions;
- e. From individuals who come to the pharmacy in groups to get narcotic prescriptions filled;
- f. That appears to have been altered or forged – verify any questionable prescription information with the Practitioner and adhere to the guidance set forth in the policy regarding Suspected Forged or Altered Prescriptions (ROPP-0059).
- g. Where the patient requests the drug by description, such as, “Mallinckrodt blues,” “M’s” or “the blue pill”; and,
- h. Where the patient appears visibly altered, intoxicated or incoherent.

The above factors are not an exclusive list and remember that you have the authority to decline to fill any prescription where, in the exercise of your professional and clinical judgment, you believe or suspect that it was not issued for a legitimate medical purpose by a Prescriber acting in the usual course of professional practice.

3. CVS Pharmacy Pharmacists should **not** refer any patient/prescription to another CVS Pharmacy if the first Pharmacist would not, in his or her professional judgment, otherwise fill the prescription.
4. Pharmacists should ordinarily only fill prescriptions if both the patient and Practitioner reside within the geographic area served by the pharmacy; any exceptions should be extraordinary, and documented in the patient files.
5. Contact the Practitioner with any concerns about the type, dosage and/or quantity of medication prescribed for a given indication (e.g., oxycodone 30 mg prescriptions for more than 120 dosage units or oxycodone > 50 MME). If the determination is made to fill the prescription, document all conversations and resolutions on the hardcopy and in the pharmacy computer system.
6. Contact the Practitioner and verify treatment if the prescription appears to be duplicative therapy, refill too soon, or if the patient has had a prescription issued by several Practitioners. If the determination is made to fill the prescription, document all conversations and resolutions on the hardcopy and in the pharmacy computer system.
7. When dispensing a controlled substance medication, such as oxycodone, amphetamine, hydrocodone, clonazepam, etc. where you have no relationship with the patient and/or the Prescriber, you should verify with the Practitioner the validity of the prescription, by requesting the diagnosis (request a diagnosis code) and other information relevant to whether the prescription should be filled or declined. Document the information on the back of the prescription and in the patient's profile in the pharmacy computer system. Note that this verification process is but one step that a Pharmacist should take to ensure that a prescription is issued for a legitimate medical purpose. Practitioner verification alone does not render a prescription legitimate.
8. Pharmacists are required to access and review Prescription Monitoring Program (PMP) data when in the professional judgment of the Pharmacist such data would assist in making a corresponding responsibility determination. Note that certain states may require Pharmacists to access the PMP in certain circumstances and you should be aware of your state's requirements.
9. CVS Pharmacy Pharmacists are required to document all steps taken to resolve red flags associated with controlled substance prescriptions in the patient profile. The

| | |
|----------------------------------|------------------------------------------------------------------|
| Document ID: ROPP-0061 | Title: Guidelines for Dispensing Controlled Substances |
|----------------------------------|------------------------------------------------------------------|

documentation must clearly justify the determination of the appropriateness of the therapy dispensed. Documentation may include, but is not limited to: diagnosis, PMP check, Prescriber conversation, treatment or taper plan. Any Prescriber office conversation notations must also include the person spoken to, the date and the time.

10. Locked-in Patients:

- a. A customer may be restricted to receiving all medication from one pharmacy location if his/her use of controlled substance prescriptions is deemed excessive by the third party agency. Once a specific pharmacy is designated as the primary location for a locked-in patient, no other pharmacy may dispense medication, especially controlled substances, for that patient. If a claim is adjudicated to the third party plan by a pharmacy that is not designated as the primary location for a locked-in patient, a rejection message would be returned by the agency.
 - i. When such a message of rejection occurs, the non-primary pharmacy cannot dispense the medication as cash, but must inform the patient to return to their primary location to be serviced.
 - ii. Only in limited, emergency situations, such as a medication is needed for treatment of an acute injury and the primary pharmacy is closed or out of stock, may the locked-in customer be serviced at an alternate location and only if issued an override by the third party agency.
- b. To ensure CVS Pharmacy Retail locations abide by the restrictions placed on Locked-in customers, the following must occur:
 - i. **For all states other than Massachusetts:** When a pharmacy receives notification that a customer has been locked into their location, a forced note must be placed into the patient profile (for example: Locked-in Medicaid Patient. CVS Pharmacy: 1234 is Primary Pharmacy. Paying cash is unacceptable.)
 - ii. **For Massachusetts Pharmacies Only:** All received notification letters must be faxed to the Corporate Professional Practice Team at 401-652-0805. Upon receipt, a Patient Level Alert message will be created by the corporate office with patient specific notes. The Pharmacy Team must also notify their Field Leader of all received notification letters.
 - 1. Responsibilities of primary Massachusetts pharmacy. The primary pharmacy must monitor the prescription utilization pattern of each member, and must exercise sound professional judgment when dispensing all prescription drugs. When the Pharmacist reasonably believes that the member is presenting a prescription that is inappropriate for his or her medical condition, the Pharmacist must contact the Prescriber to verify the authenticity and accuracy of the prescription presented. Primary pharmacies that are found on review to be dispensing drugs in a manner that is inconsistent with professional standards may be subject to administrative action by the MassHealth agency, including the recovery of payments and the imposition of sanctions, in accordance with 130 CMR 450.000: Administrative and Billing Regulations.

| | |
|----------------------------------|------------------------------------------------------------------|
| Document ID: ROPP-0061 | Title: Guidelines for Dispensing Controlled Substances |
|----------------------------------|------------------------------------------------------------------|

- c. When filling controlled substances for a locked-in patient at the primary location, it is strongly recommended that a PMP check occurs to ensure the customer has not filled elsewhere under cash payment.
 - i. When a non-primary pharmacy determines a locked-in patient is trying to obtain a controlled substance at their location and requests to pay cash, the prescription must be refused as this may be an indication of attempted diversion.
- d. If an emergency situation arises for which a non-primary pharmacy determines the need to service a locked-in patient, the agency must be called to receive an override. In the circumstance that the agency is unavailable and in the professional opinion of the Pharmacist, the member's health or safety would be jeopardized without immediate access to the prescribed drug or if the prescription is for family planning, the prescription may be processed under cash but careful documentation must occur describing the need and circumstances. The agency must then be informed of the fill at the earliest available time.
- e. Pharmacists must review all controlled substance prescriptions for the presence of red flags. If red flags cannot be resolved after due diligence, the prescription must be refused, regardless if the patient is locked-in to your pharmacy or not.

11. Pharmacists must familiarize themselves with:

- a. CVS Pharmacy policy Prescription Forgery Identification Program – Retail (ROPP-059583) details the steps to follow when prescription forgery is suspected or identified.
- b. The information contained in the DEA's Guidelines for Prescription Fraud, from Appendix D of the DEA Pharmacist's Manual.

PROCEDURES

N/A

DEFINITIONS

- 1. **CVS Health®:** CVS Health Corporation and each of its subsidiaries and affiliates.
- 2. **CVS Pharmacy®:** CVS Pharmacy, Inc., and each of its retail, mail and specialty pharmacy subsidiaries and affiliates.
- 3. **CVS Retail:** Operations of CVS Health to include the retail pharmacy and retail front store businesses.

REVIEW AND REVISION HISTORY

| Date | Revision No. | Reason for Change | Sections Affected |
|----------|--------------|---------------------------------------------------------------------------------------------|-------------------|
| 01/04/12 | 1.00 | New Policy and Procedure | All |
| 04/24/12 | 2.00 | Update Policy and Procedure | Title and Policy |
| 05/06/13 | 3.00 | Annual Review: No Change in Process or Document | N/A |
| 12/16/13 | 4.00 | Annual Review: No Change in Process or Document | N/A |
| 06/11/14 | 5.00 | Annual Review: No Change in Process or Document | N/A |
| 06/26/14 | 6.00 | Incorrect Expiration Date entered as annual review completed 6/3/2014 -updated to 6/3/2015. | N/A |

| Document ID: | Title: |
|--------------|-------------------------------------------------|
| ROPP-0061 | Guidelines for Dispensing Controlled Substances |

| | | | |
|----------|-------|-------------------------------------------------|--------------------------------------------------------|
| 06/16/15 | 7.00 | Annual Review: Transfer to Current P&P Template | No Change in Process or Document |
| 05/10/16 | 8.00 | Updated Policy and Procedure | All |
| 09/26/16 | 9.00 | Updated Policy and Procedure | All |
| 09/01/17 | 10.00 | Documentation of Filing | Policy |
| 07/10/18 | 11.00 | Annual Review | Header, Footer, or Review and Revision History, Policy |

Not for External Distribution

Confidential and Proprietary

©2018 CVS Health and/or one of its affiliates. All rights reserved.

Page 5 of 5

Not to be Reproduced Or Disclosed to Others Without Prior Written Approval

Not subject to disclosure under FOIA, including exemption 4, or otherwise
ELECTRONIC DATA = OFFICIAL VERSION / PAPER COPY = INFORMATION ONLY